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EXAMINER	
HEYER, DENNIS	
ART UNIT	PAPER NUMBER
1628	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,108	NIELSEN ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's remarks and amendments filed March 7, 2011. Acknowledgement is made of the addition of new claims 32 – 35 and the amendment to independent Claims 11, 20 and 30.

- Claims 11, 20, 22 and 30 now require that the 'evaporating' in step (iv) (Claims 11 and 20) or step (b) (Claims 22 and 30) takes place at a temperature of 25° – 100° C.
- Claims 11 and 22 require that the curing in step (v) occurs by irradiation, and,
- New Claims 32 – 35 further limit the evaporating recited in Claims 11, 20, 22 and 30 to take place at a temperature of 70° – 100° C.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 11 – 35 are currently pending.

Withdrawn Rejections

Claim rejections - 35 USC § 112 - 2nd Paragraph

The rejection of Claims 11 – 17 under 35 U.S.C. 112, second paragraph as being indefinite with respect to the term "wherein said curing is the only irradiation step in the process" (recited in Claim 11) is rendered moot and is withdrawn in response to Applicant's amendment requiring said curing occurs by irradiation.

Maintained Rejections

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 – 13, 15 – 24 and 26 – 31 *remain* rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in WO 89/09246 (published: October 5, 1989; IDS dated 3/8/2010, Foreign Patent Document Cite No. AM) in view of Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003; previously applied in the Office Action mailed 5/14/2010).

This rejection is maintained but has been modified to address Applicant's amendments to Claims 11, 20, 22 and 30 which specify that the evaporating step is carried out at a temperature of 25° – 100° C and the curing step is carried out by irradiation which is the only irradiation step in the process.

Howard teaches solid shaped structures having a surface coated with a crosslinked hydrophilic polymer and a process for preparing said structures, the coating being durable and exhibiting a low coefficient of friction when wet (Abstract). The coating process is carried out by: 1) contacting (applying or dipping) a solid surface with a solution of crosslinkable hydrophilic polymer and optionally, a free radical initiator (an additive), 2) drying the coated surface and, 3) crosslinking (curing) the hydrophilic polymer of the dried coated surface (page 4, lines 18 – 34, Claim 41).

Crosslinking is carried out by exposing the dried coated surface to either heat, UV radiation in the presence of a free radical initiator or, subjecting it to electron beam radiation in the absence of additives (page 4, lines 1 – 15; page 6, lines 4 – 10).

Accordingly, with respect to the nature of the curing step in amended Claims 11, 20 and 30, Howard teaches a curing step (Step 3, above) carried out by irradiation which is the only irradiation step in the process. Further, with respect to amended

Claims 11, 20, 22 and 30, drawn to evaporating at least a part of the vehicle at a temperature of 25° – 100° C, Howard teaches, in e.g. Example 1, air-drying the coated film (i.e. evaporating the solvent vehicle) at 25° C.

Howard teaches solvents suitable for dissolving the hydrophilic polymer include water, methylene chloride, ethanol, etc. (page 8, lines 5 – 14). Accordingly, the polymer solution which is applied to the solid surface of Howard comprises at least one solvent (instant Claims 13 and 24). The curing (crosslinking) step of Howard does not require rewetting the dried coated surface as recited in Claims 11 and 20. As noted above, the method of Howard only requires a single application (dipping) step (see also Examples 1 – 11; instant Claims 12 and 23). Howard teaches the preferred hydrophilic polymer is polyvinylpyrrolidone (PVP) (page 20, lines 18 – 20; instant Claims 16, 21, 27 and 31) and is present in the solution applied to the surface to be coated at ~ 3 weight percent (Examples 1 – 9; instant Claims 11, 20, 22 and 30).

Howard teaches the coatings are suitable for medical application, for example, catheters, scopes, tubes and wound dressings (i.e. medical devices). Howard teaches, in Example 9, a method for coating a polyurethane catheter, the method steps consisting of dipping a polyurethane catheter tube (i.e. providing a medical device with a substrate polymer surface) into a methylene chloride solution containing 3 weight percent polyvinylpyrrolidone (PVP) and 1 weight percent benzoyl peroxide (an additive) (i.e. providing a solution comprising a polymer and an additive); applying said solution to the catheter substrate polymer surface); drying under nitrogen overnight (i.e. evaporating at least a part of the solution (vehicle) on the polymer surface, which is

reasonably construed based on Example 1 above and, absent evidence to the contrary, as drying at about room temperature, taken to be about 25° C); and crosslinking the at least partially dried coated surface by heating 1 hour in air at 110 °C (i.e. curing the hydrophilic polymer).

It is noted that although Howard does not teach, in Example 9, crosslinking by the required single irradiation step, the generic teaching of crosslinking (curing) by heat, UV radiation or electron beam radiation, noted above, renders obvious modifying Example 9 to include a crosslinking step by heat or irradiation (see page 4, lines 1 – 15; page 6, lines 4 – 10).

It is noted that Howard teaches the crosslinked coating prepared in Example 9 is subsequently washed in water and then tested for coefficient of friction. Such a 'step' (subsequent washing) is not recited in Claim 22 which consists of only the applying, drying and crosslinking steps. However, Howard teaches that subsequent washing in water at physiological temperature is carried out only to determine the durability of the crosslinked coating prior to testing its coefficient of friction and is therefore not a process step in preparing said coating (see page 9, lines 13 – 20).

As noted above, Howard teaches the process of coating a medical device (a catheter) by applying a catheter to a solution containing 3 weight % of the hydrophilic polymer PVP and an additive (benzoyl peroxide). However, the coating solutions of Howard do not contain a plasticizer as required in the method Claims 11, 20 and 30, and the coated medical device product Claims 17 – 19 and 28 – 29.

Hunter teaches compositions and methods for coating medical implants (Title) and, further, teaches polymer coatings comprising triethyl citrate as a plasticizer in order to increase the flexibility of the coating (p [0095], [0109]). Hunter is silent on the physical properties of triethyl citrate recited in the instant Claims. However, as evidenced by Table 1 (page 10) of the present specification, triethyl citrate has the properties recited in instant Claims 11, 18 – 20, 22, 29 and 30 (i.e. solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20).

It would have been *prima facie* obvious to one of ordinary skill in the art to modify the polymer solution in the coating method of Howard to include the plasticizer triethyl citrate. One would have been motivated to do so with a reasonable expectation of obtaining a coating on a catheter with increased flexibility because Hunter teaches triethyl acetate is a plasticizer recognized in the art to increase the flexibility of medical device coatings.

Claims 14 and 25 *remain* rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in WO 89/09246 (published: October 5, 1989) and Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003), as applied to Claims 11 – 13, 15 – 24 and 26 – 31 above, and further in view of Larsen *et al.* in US patent 5,484,565 (published January 16, 1996; previously applied in the Office Action mailed 12/17/2010).

Howard in combination with Hunter renders obvious the limitations of instant Claims 11 – 13, 15 – 24 and 26 – 31. With respect to instant Claims 14 and 25, the

references disclose that the polymer solution has the ranges claimed for the solution containing the hydrophilic polymer and additives but does not teach the recited % weight range of plasticizer.

Larsen teaches methods for making polymer articles such as catheters which are contacted with a solvent and a plasticizer softer and more pliable or flexible (Abstract). Larsen teaches that when the plasticizer is combined with the swelling agent (solvent) the resulting solution preferably contains 50 – 90 % of the solvent and 1 – 50 % of the plasticizer (column 11, lines 14 – 27). The ranges taught by Larsen substantially overlap those recited in instant Claims 14 and 25. See MPEP 2144.05: In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to employ the range of plasticizer (1 – 40 %) and solvent (50 – 90 %) taught by Larsen in the method of Howard and Hunter to prepare a coated catheter. One would have been motivated to do so because these ranges have been taught Larsen to be suited to beneficially modify the flexibility or pliability of a catheter.

New Rejections

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in WO 89/09246 (published: October 5, 1989) and Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003), as applied to Claims 11 – 13, 15 – 24 and 26 – 31 above, and further in view of Madsen *et al.* in US 2002/0037943 (published: March 28, 2002; IDS dated 3/6/2006, Cite No, AH; previously applied in the Office Action mailed 5/14/2010).

This new ground of rejection is necessitated by the limitation of "wherein….evaporating takes place at a temperature of 70^{o} – 100^{o} C" *recited in new Claims 31 – 35.*

As noted above, Howard in combination with Hunter renders obvious a medical device and the method of preparing a cross-linked hydrophilic coating on the polymer surface of a medical device as recited in instant Claims 11 – 13, 15 – 24 and 26 – 31.

The combination of references renders obvious evaporating a carrier solvent by either "air drying" or specifically drying at 25°C and also discloses that the crosslinking step must be carried out on relatively dry hydrophilic polymer since the presence of water may produce an adhesive rather than a low friction surface (i.e. any water in the carrier solvent used to coat the medical device must be evaporated; see Howard, page 6, lines 19 – 24) but does not render obvious evaporating at a temperature of 70° – 100° C as recited in new Claims 32 – 35.

Madsen teaches a method for sterilizing a medical device having a hydrophilic coating wherein the resulting coated devices show significantly increased and prolonged water retention and lower friction coefficient when wet (Abstract).

In Example 1 (see also Claim 12), Madsen teaches a method for preparing said low friction medical devices (a catheter) comprising applying a polyvinylpyrrolidone (PVP) solution to a catheter surface, drying the coated catheters for 30 minutes at 70° C and, exposing the coated catheters to UV light (i.e. cross-linking or curing).

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to evaporate the carrier solvent (i.e. the vehicle) at 70° C prior to crosslinking in the method used to prepare a low friction coated medical device rendered obvious by Howard in combination with Hunter. One would have been motivated to do so, with a reasonable expectation of success, because Madsen teaches

that removing the solvent (vehicle) at 70° C from a catheter (medical device) coated with the same polymer (PVP) as Howard and Hunter provides, following a subsequent crosslinking (curing) step, a coated medical device (catheter) with a low friction surface. Finally, it would have been obvious to increase the temperature to 70° C in the evaporating step to better ensure a dry polymer surface because water is an alternative solvent taught by Howard to coat the catheter surface with a polymer solution prior to drying and crosslinking. Howard discloses that the crosslinking step must be carried out on a relatively dry hydrophilic polymer since the presence of water may produce an adhesive rather than a low friction surface.

Response to Arguments

Applicant argues that "Howard fails to teach an evaporation step that takes place at a temperature from 25°-I00°C. Instead, Howard specifically teaches that the evaporation step is done at room temperature (i.e. without heating), specifically distinguishing between the air drying step and a subsequent curing step (which involves heating). Nothing in Howard or either of the secondary references teaches or suggests that the evaporation step should take place at a temperature of 25°-I00°C" (Remarks, pages 11 – 12, bridging paragraph).

This argument has been carefully considered but is not found to be persuasive because, as pointed out in the maintained 103(a) rejection above, Howard teaches in Example 1, air drying at 25°. Accordingly, the teaching of "drying" or "air-drying" without

specifying a temperature, in any of the Examples of Howard, is also reasonably construed as taking place at a temperature of 25°.

Applicant traverses the Examiner assertion "that a person of ordinary skill in the art would have been motivated to use the plasticizer of Hunter in Howard's process because Hunter teaches that the plasticizer increases the flexibility of the coating. Applicant argues that "Howard's coating is not described as needing to be more flexible; thus, a person of skill in the art reading Howard would have had no reason to use Hunter's plasticizer in Howard's process".

Applicant argues that "Only hindsight reconstruction based on knowledge of Applicants' invention suggests the combination of the references in the manner required by the rejection" and that "nothing in Hunter teaches or suggests that its plasticizer would provide the properties to the coatings which are actually observed in coatings prepared using the presently claimed methods, namely high abrasion resistance and a low friction coefficient when wet" (Remarks, page 12, 2nd paragraph).

The advantageous property of Hunter's plasticizers, increasing the flexibility of the coating, while different from that stated by Applicant (high abrasion resistance and a low friction coefficient when wet), would clearly be recognized by one of ordinary skill in the art as a desirable property of a medical device such as a catheter. Thus one of ordinary skill in the art, guided by the teachings of Hunter, would be motivated to modify the low friction coating Howard with a plasticizer known to improve coating flexibility (Hunter) with a reasonable expectation of providing a coating that is both flexible and low friction.

In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to improve the coating properties of a medical device such as a catheter. Accordingly, it would have been obvious to have examined triethyl citrate as one of the two plasticizers disclosed by Hunter (p [0109]) to improve the flexibility of the coating on a medical device.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant Case the applied 103(a) rejection combines a low friction coating on a medical device (Howard) with a plasticizer (Hunter) known to increase the flexibility of a coating on a medical device, knowledge of each being within the level of ordinary skill at the time the claimed invention was made.

Conclusion

Claims 11 – 35 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Friday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached at (571)272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DENNIS HEYER/
Examiner, Art Unit 1628

/Timothy P Thomas/
Primary Examiner, Art Unit 1628